

**510(K) SUMMARY  
OF SAFETY AND EFFECTIVENESS**

**JUL 30 2014**

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the G-FORCE® Gen 2 Ti Suture Anchor System.

Submitted By:	Wright Medical Technology, Inc.
Date:	April 17, 2010
Contact Person:	Dmitri Falkner
	Regulatory Affairs Specialist I
Proprietary Name:	<b>G-FORCE® Gen 2 Ti Suture Anchor System</b>
Common Name:	Soft Tissue Anchor
Classification Name and Reference:	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener - Class II
Device Product Code and Panel Code:	Orthopedics/87/MBI/HWC
Predicate Device:	G-FORCE® Ti Suture Anchor System (K100579)

**DEVICE INFORMATION**

**A. DEVICE DESCRIPTION**

The G-FORCE® Gen 2 Ti Suture Anchor is a sterile, single-use, hand-held device intended to aid in the attachment of soft tissue to bone. The G-FORCE® Gen 2 Ti Suture Anchor comes preloaded with non-absorbable polyethylene sutures, needles and titanium alloy anchors. The anchors are available in a variety of sizes with correspondingly sized sutures.

**B. INDICATIONS FOR USE**

The G-FORCE® Gen 2 Suture Anchor System is indicated for use:

- In the repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;
- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;

- In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments, Tendon Transfers, tendon reattachments, and ligament reconstructions of the midfoot, forefoot, and hindfoot procedures associated with flatfoot reconstruction, hindfoot deformity, midfoot reconstruction, lateral/medial ankle reconstruction or instability, Hallux Valgus or Varus, and MTP instability including:
  - Achilles reattachment/reconstruction
  - Flexor Digitorum Longus Transfer
  - Flexor Hallucis Longus Transfer
  - Extensor Hallucis Longus Transfer
  - Broström Procedures
  - Peroneal Tendon Relocation
  - Capsule Repair
  - Deltoid reconstruction / reattachment
  - Plantar Plate Repair
  - Spring Ligament Repair

### C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use of the G-FORCE® Gen 2 Ti Suture Anchor System have a larger scope when compared to that of the predicate. As the technological characteristics by which the intended use is achieved is the same for both the subject and predicate systems. As such, the inclusion of additional indications does not constitute a deviation from substantial equivalence.

The design characteristics of the subject device do not raise any new types of questions in terms of either safety or efficacy. Based on the evidence submitted in this 510(k), the subject device can be expected to perform in a manner equal or superior to the predicate device and is substantially equivalent.

### D. PERFORMANCE DATA

Bench testing was used to demonstrate that the pullout strength characteristics of the G-FORCE® Gen 2 Ti Suture Anchor System are substantially equivalent to the predicate. The safety and effectiveness of the G-FORCE® Gen 2 Ti Suture Anchor System is adequately supported by the pullout testing performed, substantial equivalence information, literature review, and comparison of design characteristics provided within this premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

July 30, 2014

Wright Medical Technology, Incorporated  
Mr. Dmitri Falkner  
Regulatory Affairs Specialist  
1023 Cherry Road  
Memphis, Tennessee 38117

Re: K141011

Trade/Device Name: G-FORCE® Gen 2 Suture Anchor System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: MBI, HWC  
Dated: July 2, 2014  
Received: July 3, 2014

Dear Mr. Falkner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Lori A. Wiggins**

for

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**Indications for Use**

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement on last page.

510(k) Number (if known)

K141011

Device Name

G-FORCE® Gen 2 Suture Anchor System

**Indications for Use (Describe)**

The G-FORCE® Gen 2 Suture Anchor System is indicated for use:

- In the repair of shoulder instability secondary to Bankart lesion, rotator cuff tear, a slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear/separation, or capsular shift or capsulolabral reconstruction;
- In the repair of elbow instability secondary to biceps tendon detachment, tennis elbow, or ulnar or radial collateral ligament tear/separation;
- In the repair of hand/wrist instability secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament;
- In the repair of knee instability secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band tenodesis;
- In the repair of foot/ankle instability secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments, Tendon Transfers, tendon reattachments, and ligament reconstructions of the midfoot, forefoot, and hindfoot procedures associated with flatfoot reconstruction, hindfoot deformity, midfoot reconstruction, lateral/medial ankle reconstruction or instability, Hallux Valgus or Varus, and MTP instability including:
  - Achilles reattachment/reconstruction
  - Flexor Digitorum Longus Transfer
  - Flexor Hallucis Longus Transfer
  - Extensor Hallucis Longus Transfer
  - Brostrom Procedures
  - Peroneal Tendon Relocation
  - Capsule Repair
  - Deltoid reconstruction / reattachment
  - Plantar Plate Repair
  - Spring Ligament Repair

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Casey L. Hanley, Ph.D.  
Division of Orthopedic Devices